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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,290

03/03/2004

Frank S. D'Amelio SR.

45437

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01/21/2010

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SUITE 600

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/791,290

**Applicant(s)**

D'AMELIO ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7, 10-13, 16, 22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 11-13, 16, 22 and 24-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' arguments in the Request for Continued Examination, filed October 28, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 1, 9 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained. Claim 9 is cancelled.

#### **Applicant's Arguments**

Applicant argues Romanowski et al. does not disclose or suggest to one of ordinary skill in the art the claimed oral composition comprising each of the recited components in the claimed amounts. Romanowski et al. does not disclose an amount of each of the components disclosed in Romanowski et al. and only discloses a list of

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possible components but provides no guidance to one skilled in the art to combine the components in the manner of the claimed invention. The Examiner's random selection of components disclosed in Romanowski et al. does not lead one of ordinary skill in the art to the claimed invention. There is no basis or rationale to select and combine specific components from the broad list of components outlined in Romanowski et al. and the rejection is clearly based on hindsight. The specific combination of components in the claimed invention exhibits a particular function and provides a specific property to inhibit inflammation. Each of the components in the amounts provides a specific function which when combined, provide a result that is not exhibited or suggested by the composition of Romanowski et al. The enhanced performance of the claimed composition is obtained by the specific combination as claimed.

#### Examiner's Response

In regards to the combination of components, as asserted before by the Examiner, it is *prima facie* obviousness to select a known material based on its suitability for its intended use and the ingredients in the claims are disclosed by Romanowksi et al. as agents that kill microorganisms, reduce inflammation and rebuild damaged tissue. Applicant asserts inflammation is the major function of the recited compositions and appears to assert some kind of unexpected results but does not appear to show any support for these results. Therefore Romanowski discloses the function of the composition. Further each component recited in the instant claims is known in the art to have a particular function (see The Periodontal Solution: Healthy

Gums Naturally cited below). Therefore it would have been obvious to combine these components for their functional value. The suggestion for adding the components together is the recitation that the components may be included into the compositions in mixtures. In regards to Romanowski being directed primarily to a composition containing xylitol and an antimicrobial agent, the claims do not exclude xylitol and the recited components encompass an antimicrobial agent. Additionally the combination of components recited in the instant claims appear to make up a bioactive agent included in an oral composition and thus would encompass oral compositions comprising xylitol. In regard to the Examiner using hindsight, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Romanowski suggests using the components for their functional value in the disclosed compositions and thus it would have been obvious to combine two or more of the listed components and incorporate them into the compositions of the reference based on this disclosure and not on knowledge gleaned only from the Applicant's disclosure.

2) Claims 1-3, 7, 9, 11-13, 16, 22, 24, 25 and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Harrison (The Periodontal Solution: Healthy Gums Naturally) and Rice et al. (US 5,741,138). The rejection is maintained. Claims 9 and 29 are cancelled

Applicant's Arguments

Applicant argues Close does not disclose or suggest a holistic extract of *Centipeda cunninghami* as defined in the specification and as recited in claim 1. Close provides no suggestion to one skilled in the art of a composition containing the claimed holistic extract of *Centipeda* in combination with the coenzyme Q10, aloe vera, folic acid, Vitamin E, gota kola, bio- saponin, thyme oil and olive leaf oil as in the claimed invention. Harrison and Rice et al. disclose various plant components, but provide no suggestion to one skilled in the art to combine the components in the manner of the claimed invention. The Action clearly provides no rationale or articulated reasoning for one skilled in the art to combine the components in the claimed manner. The claimed invention includes a specific combination of components and amounts of the components to provide a moisturizing feel to the mouth while being effective in inhibiting inflammation and inhibiting the growth of oral bacteria. In contrast, the compositions disclosed in Close, Harrison and Rice et al. typically exhibit an astringent or dry feeling to the mouth. One skilled in the art would not be motivated to select the components of Close, Harrison and Rice et al. in the random manner suggested in the Action. Moreover, one skilled in the art would have no reasonable expectation of success in

inhibiting the growth of oral bacteria and inhibiting inflammation of oral tissue of the claimed composition based on the disclosures of Harrison, Close and Rice et al.

Examiner's Response

As previously asserted in regard to "holistic extract", Applicant discloses a "holistic extract" can be obtained by various methods. It is also submitted that the resulting extract is a holistic mixture of active components in "substantially the same ratio" as the active components that are present in the native plant material. The term "substantially" is not defined and it cannot be ascertained what constitutes "substantially the same ratio". Further, it appears the "holistic extract" may be obtained by any of the solvents disclosed by the instant specification, which discloses a suitable polar, non-polar, semi-polar or mixtures thereof, thus it appears that any extract that is obtained by any one of the numerous solvents would be a "holistic extract". Further, Close discloses the extract is obtained from an aqueous alcoholic extract, therefore encompassing "holistic" as described by Applicant's instant disclosure. The reference also suggests incorporating abrasives, solvents, humectants, detergents, binders, herbal actives (e.g. aloe vera), essential oils (e.g. eucalyptus oil, peppermint oil), deodorizing agents (e.g. chlorophyll) and/or suspension agents (e.g. hydrogenated castor oil). The secondary references provide the functional value of components encompassed by these categories, thereby giving motivation as to why one of ordinary skill in the art would have used these components in conjunction with the compositions of Close.

Furthermore it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See MPEP 2144.07, which further supports the instant rejection. Where it would have been obvious to have combined individually known ingredients, it is not necessary that the individual ingredients be disclosed in one reference so long as their expected function is known. In the instant case, the functions of each component is known and disclosed by Harrison and Rice. Since Close suggests incorporating these types of material into the disclosed compositions, this is motivation as to why one of ordinary skill in the art would want to incorporate these components into the compositions of Close to obtain their known functions.

One of ordinary skill in the art would reasonably expect the compositions of the combined references to provide a moisturizing feel to the mouth while being effective in inhibiting inflammation and inhibiting the growth of oral bacteria because these are properties attributed to some of the listed components. For instance Echinacea possess anti-inflammatory properties, calendula is an anti-fungal and reduces inflammation and aloe vera is an antibacterial and reduces inflammation. Further, the compositions of Close alone would produce these properties because they are disclosed to have anti-bacterial and anti-inflammatory properties. Applicant does not appear to provide any support to show that the compositions of the instant claims have superior properties or provide unexpected properties to make them non-obvious over the combined references.

***Allowable Subject Matter***



Claims 10 and 26 are allowable as previously stated.

Claims 1-3, 7, 11-13, 16, 22 and 24-25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612